

## REMARKS

### I. Amendments

By this amendment, claims 1, 9-11, 13 and 18-21 have been amended and new claims 22-24 have been added.

This amendment adds no new matter to the specification. Support for this amendment is found in the specification and claims as filed.

No amendment of inventorship is necessitated by this amendment.

### II. Discussion of the Advisory Action

The recent Advisory Action acknowledges withdrawal of a previous rejection under 35 U.S.C. Sec. 102(b) over Ohno *et al.* (U.S. Patent No. 5,958,453) for the record, which Applicants appreciate. The Examiner also indicates that the rejection under 35 U.S.C. Sec. 103(a) over Ohno *et al.* (U.S. Patent No. 5,958,453) in view of Shimizu *et al.* (U.S. Patent No. 6,299,904) is withdrawn. Applicants acknowledge the withdrawal, and believe that it was withdrawn because Shimizu *et al.* is not proper art, though no reason was given.

The Advisory Action is somewhat confusing, however as it indicates that claims 9-11 are allowed, but does not indicate that the amendments filed June 10, 2003 would be entered. Moreover, there is also no indication that the 35 U.S.C. Sec. 103(a) rejection over Ohno *et al.* (U.S. Patent No. 5,958,453) in view of Shashoua *et al.* (U.S. Patent No. 5,795,909) has been overcome, which would seem to be necessary if claims 9-11 were to be allowable.

In this Preliminary Amendment, Applicants are re-presenting the claim modifications of their response dated June 10, 2003 along with the arguments related to the 35 U.S.C. Sec. 103(a) rejection over Ohno *et al.* and the 35 U.S.C. Sec. 103(a) rejection over Ohno *et al.* in view of Shashoua *et al.*, which they believe are the only outstanding rejections.

### III. Discussion of the Rejection under 35 U.S.C. Sec. 103(a) over Ohno *et al.*

Claims 1-7 and 13-21 have been rejected under 35 U.S.C. Sec. 103(a) as allegedly obvious over Ohno *et al.*, U.S. Patent No. 5,958,453. Applicants respectfully traverse the rejection.

As an initial matter, Applicants note that claim 3 has previously been cancelled.

By this amendment, independent claims 1 and 18-21 have been amended to recite that the solid preparation (or tablet) is buccally dissolved in from about 5 to about 50 seconds. This amendment adds no new matter to the specification. Support for the amendment may be found *inter alia* at page 27, lines 1-14.

The cited reference does not teach or suggested the solid preparations as set forth in the pending claims as amended. In the '453 reference, comparative examples are presented, wherein formulations with and without L-HPC are evaluated in terms of dissolution time. In every instance, the formulations including L-HPC demonstrate significantly longer dissolution times.

Specifically, in Example 4 in col. 8 of the cited reference, **without L-HPC** a dissolution time of 45 seconds is recorded as shown in Table 4, in col. 9, whereas **with L-HPC** (Comparative Example 4) a buccal dissolution time *more than twice slower* (105 seconds) is recorded. In Example 5 in col. 9 of the cited reference, **without L-HPC** a dissolution time of 28 seconds is recorded as shown in Table 6, in col. 9, whereas **with L-HPC** (Comparative Example 5) a buccal dissolution time which is *three times slower* (85 seconds) is recorded.

No one skilled in the art would have been motivated to add L-HPC to a preparation to achieve the claimed range for disintegrability in light of the experimental results presented. Therefore, the '453 reference teaches away from the present invention, as set forth in the claims as amended.

Claims 2, 4-7 and 13-17 depend upon claim 1. Applicants submit that the more specific dependent claims are also unobvious for the reason provided above.

Therefore, Applicants respectfully request withdrawal of the 35 U.S.C. Sec. 103(a) rejection over Ohno *et al.*

IV. Discussion of the Rejection under 35 U.S.C. §103(a) over Ohno *et al.* in view of Shashoua *et al.*

The rejection of claims 10-12 under 35 U.S.C. Sec. 103(a) as allegedly obvious over the Ohno *et al.*, U.S. Patent No. 5,958,453 in view of Shashoua *et al.*, U.S. Patent No. 5,795,909 has been maintained.

As an initial matter, Applicants note that claim 12 was previously cancelled.

For the two remaining independent claims which are subject to this rejection, Applicants hereby incorporate their arguments of Sec. III above into this Section. Claims 10 and 11 have been amended to recite that the solid preparation is buccally dissolved in from about 5 to about 50 seconds. The '453 reference does not apprise one skilled in the art of how to obtain such a rapid dissolution when the formulation includes L-HPC. Rather, one skilled in the art reading the cited reference would have been taught that to achieve the presently claimed rapid dissolution time, L-HPC should be eliminated from the formulation.

The deficiencies of Ohno *et al.* are not cured by Shashoua *et al.*

Therefore, Applicants respectfully request withdrawal of the rejection under 35 U.S.C. Sec. 103(a) over Ohno *et al.*, U.S. Patent No. 5,958,453 in view of Shashoua *et al.*, U.S. Patent No. 5,795,909.

V. Discussion of New Claims 22-24

By this amendment, new claims 22-24, directed to orally disintegrable tablets composed of fine granules of active ingredient, have been added. This amendment adds no new matter to the specification. Support for the new claims may be found at page 16, line 19 – page 18, line 1 *inter alia*.

VI. Conclusion

Reconsideration of the claims as amended in view of the arguments made above is solicited. Should the Examiner believe that a conference with Applicants' attorney would advance prosecution of this application, he is respectfully requested to call Applicants' attorney.

Respectfully submitted,

Dated: September 26, 2003

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